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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,628	ANDERSON ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-48 and 59-77* is/are pending in the application.

4a) Of the above claim(s) *69-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48 and 59-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I claims 46-48 and 59-68 in the reply filed on 11/18/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant further added new method claims 69-77 which are directed to the method of using the elected device and request examination of these claims with the device claims. This is found not persuasive because the newly added claims differ in scope as indicated by their distinct modes of operation. As such, claims 69-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being non allowable generic or linking claims. This requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-23, 34, 36-39 and 42-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcenyac et al (US 2004/0146547) and Granger et al (US 5,149,538) in view of Church (6,660,901) **are withdrawn** in view of Applicant's amendment to claims.

However, upon further consideration a new ground(s) of rejection is made as follow.

Claims 46-48 and 59-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcenyac et al (US 2004/0146547) in view of Granger et al (US 5,149,538) and Jospeph Greensher et al (Pediatrics, Vol. 80(6), 949-951, 1987).

Applicant's claims are drawn to a disposal system for skin-worn transdermal patch devices containing abusable substances, a layer containing anti-abuse substance such as antagonists, irritants or activated carbon and closure means for closing said container.

Marcenyac teaches an article (a transdermal patch) includes a reservoir housing a dye and/or medicament inactivating agent (which would read on anti-abuse substance) in communication with the reservoir that is released when the reservoir is opened or revealed (0009). And further, the article may include a pocket (which would read on flexible pouch) having a sealable opening and formed between first and second portions of the opposite side of the inner layer, wherein the opening is optionally sealed

by a flap covered at least in part by a permanent pressure (0014). The disposing of a transdermal patch includes placing a transdermal patch within the article, sealing the patch (which would read on adhesive seal) within a pocket of the article, such that the article releases the inactivating agent when the reservoir is opened and thus the article prevents of hinders misuse of the active agent contained in the transdermal dosage form or the disposal of the above article by folding the article so that opposite sides of the medicament layer are permanently sealed by the second adhesive (0022 and 0029). Further, article includes a medicament layer containing an opiate e.g. fentanyl; the inactivating agent include opioid-neutralising antibodies; narcotic antagonists such as naloxone, naltrexne and nalmedrne; or irritating agents such as scopolamine, ketoamine, atropine or mustard oils or any combinations thereof (0112 and 0114). And in practice, if the active agent in a transdermal patch to be disposed of by placing it in the present article were an opioid, the inactivating agent renders the active agent unavailable through inactivation, such as for example chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like; or something similar thereto. One or more inactivating agent(s) may be used (0099). And further discloses that it is known in prior art (US 5,804,215) to Cubbage et al. relates to disposal system for a transdermal patch comprising a pouch for transport of the patch and disposal system encapsulates a trasndermal patch and prevents access to it.

Note, Marcenyac et al. teaches use of various anti- abuse substances directly related to effective in preventing abuse, were an opioid, the inactivating agent could be a chemical or denaturing agent that would alter residual opioid molecules in the dosage form and make them inactive (0100). Since the inactivating agents is directly related to anti-abuse substance, and the prior art teaches the same subject matter (disposable of transdermal patch containing residual or unused opioid in a separate pouch) by similar process, it is examiner's position that, in the absence of evidence to the contrary, a suitable specific anti- abuse substance is also either anticipated by Marcenyac, or obviously provided by practicing the invention of prior art. It should be noted that where claimed and prior art products are shown to be identical or substantially identical in composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See MPEP § 2112.01.

Marcenyac fails to teach release of irritating agents or antagonist agents upon attempt to solvent extract and activated carbon as anti-abuse substance in a disposable container.

Granger teaches a transdermal adhesive patch comprising opioid such as buprenorphine or salts and one or more anit-abusable substance in an effective amount to substantially attenuate the euphorigenic effect of the opioid, and it is releasable from the dosage form upon being ingested or substantially immersed in water, alcohol or other solvent and barrier means which separates said antagonist substance from said opioid, said barrier means being impermeable to said opioid and to said antagonist

substance, which would read on lightly adhering impermeable separator membrane (col. 3 line 25-40). Additional disclosure includes that the impermeable barrier separates the opioid in the dosage form from the antagonist substance to prevent any adverse chemical reactions or ion exchanges between the opioid and the antagonist, and to prevent release of the antagonist unless the dosage form is ingested or immersed in water, alcohol or other solvent. If ingested or solvent extracted, the antagonist substance substantially attenuates the euphorigenic effect of the opioid, thereby reducing the tendency for misuse and abuse of the dosage form (col. 2 line 55-64).

Joseph teaches that activated charcoal has the capability of inactivating a larger quantity of an ingested substance than the approximately 30% that could be removed by syrup of ipecac-induced vomiting. The effectiveness of activated charcoal lies in its small particle size and large surface area, allowing the adsorption of a variety of chemical agents by offering alternative binding sites and thereby reducing their absorption from the gastrointestinal tract (page 949). Compounds adsorbed by activated charcoal include analgesic, morphine, narcotics, nicotine opium, quinine and the like (page 950). Additional disclosure includes that a recent study indicated that activated charcoal may be the more appropriate initial emergency department treatment for ingested chemical and drug overdoses.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate releasable forms of irritating or antagonist agent and activated charcoal into the Marcenyac's transdermal patch. The person of ordinary skill in the art would have been motivated to make those modifications because Granger

teaches that dosage form provides the benefit of being resistive to misuse because the opioid antagonist is released from the dosage form upon being ingested or substantially immersed in water or other solvents, thereby reducing the tendency for misuse and abuse of the dosage form (col. 2 lines 55-65). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because both Marcenyac and Granger teaches a transdermal adhesive patch that can be used in the same field of endeavor, such as for example chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like; or something similar thereto.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate activated charcoal into the Marcenyac's transdermal patch. The person of ordinary skill in the art would have been motivated to make those modifications because Joseph teaches that activated charcoal has the capability of inactivating a larger quantity of an ingested substance than the approximately 30% that could be removed by syrup of ipecac-induced vomiting and reasonably would have expected success because the activated charcoal has power to adsorb various chemical and drug overdoses persists for several hours after administration and has been referred to as "the catch-up phenomena."

Response to Arguments

Applicant's arguments filed on 09/01/2009 have been fully considered but they are not persuasive.

Applicant argues that Marcenyac fails to disclose or suggest a disposal device or technique that deactivates the medicament on contact during normal disposal.

This is not found persuasive, since the Marcenyac reference teaches various inactivating agent when contacted with or a medicament or active agent to be placed in the article, renders the active agent unavailable through inactivation, such as for e.g. chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability (0099). Similarly, the inactivating agent could be a non- opioid with distressing or dysphoric properties if absorbed that made abuse unpeeling (0100). Further the inactivating agent may be released when the dosage form is handled in a particular manner, squeezed with sufficient force, or if the dosage form is abused, such as for example, is chewed, soaked, subjected to extraction, smoked, or the like. Thus, this article could be used, for example, to inactivate any residual active agent when the dosage form is discarded (0110). It is well established that the claims are given the broadest reasonable interpretation during examination in light of the supporting disclosure as it would be interpreted by one of ordinary skill in the art, In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023,1027-28 (Fed. Cir. 1997); In re Am. Acad. of ScL Tech. Ctr., 367 F.3d 1359,1364, [70 USPQ2d 1827] (Fed. Cir. 2004). Further, it has been held that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. In re Zletz, 893 F.2d 319,

321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). In the present case, the inactivating agents disclosed by the prior art is released when the reservoir is opened or revealed, and inactivating material may contact and/or penetrate the medicament layer, optionally altering, damaging, and/or inactivating the medicament contained therein.

Applicant also argues that the container is "configured such that insertion of said skin-worn patch device properly oriented into said container causes said abusable substance in said skin-worn patch device to contact said deactivating material." This element is simply not present in Marcenyac.

This argument is not persuasive because Marcenyac teaches that upon expiration of the proscribed term of use of a transdermal patch containing an opioid, the patch is peeled off the skin of the user and disposed of using a disposable article depicted in FIG. 1(b). In utilizing this article, the patch is placed generally in the center of the inner layer and the outer layer is folded in on the inner layer, creating a pouch that sandwiches the used patch with the material reservoir formed between the inner and outer layers. An adhesive is used to secure the inner layer to the outer layer. The patch may also be held within the reservoir by adhesive contained within the material reservoir (0120). Once the used patch is encased in the disposal device and the layers are sealed, when the device is tampered with, the inactivator releases an opioid receptor antagonist that mixes with any residual medicament in the patch, thereby providing a material which will counter the activity of any opioid remaining in the used patch (0121) or alternatively, the inactivating agent is contacted with the medicament

when the patch is folded such that the first region contacts the second region, optionally altering, damaging and/or inactivating the medicament contained within (0098).

Applicant also argues that the Marcenyac device contemplates co-formulation of a dye with the inactivating agent so as to produce an identifying stain on an individual attempting to tamper with the device. Activated carbon, as a non-specific adsorption agent, would bind with the dye and thus not allow the identifying dye transfer to the individual.

This argument is not persuasive because Marcenyac teaches that if the active agent in a transdermal patch to be disposed of by placing it in the present article were an opioid, the inactivating agent could be a chemical or denaturing agent that would alter residual opioid molecules in the dosage form and make them inactive. The inactivating agent could be an opioid receptor that would bind the residual opioid into an insoluble ligand-receptor complex. The inactivating agent could also be an opioid receptor antagonist, preferably with greater specificity and/or affinity for the receptor than the opioid, which would be isolated or delivered with the residual opioid upon misuse and compete with the residual opioid for the opioid receptor, thereby defeating the purpose of misusing the opioid. This would render the residual opioid useless in vivo. Therefore, the inactivating material of Marcenyac device can be substituted with activated charcoal for adsorption of residual opioid in the patch and inactivating the medicament contained within.

Applicant also argues that neither the Marcenyac device nor any other of the cited references contemplate or suggest a deactivating system that includes

incorporation of an agent selected from the group consisting of antagonists, irritants and mixtures thereof onto a portion of activated carbon.

In response to applicant's arguments regarding Marcenyac and other cited reference, as "In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) states, "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose". As this court explained in Crockett, 126 USPQ 186, 188 (CCPA-1960), the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant product claims, given the teaching of the Marcenyac use of various anti- abuse substances directly related to effective in preventing abuse, were an opioid, the inactivating agent could be a chemical or denaturing agent that would alter residual opioid molecules in the dosage form and make them inactive and Granger discloses a transdermal adhesive patch comprising opioid such as buprenorphine or salts and one or more anit-abusable substance in an effective amount to substantially attenuate the euphorigenic effect of the opioid and Church discloses a patch for topical application to the skin includes a charcoal based composition for the purpose of adsorbing toxins, bacteria, fungus, carcinogens, and other harmful pathogens, it would have been obvious to use Marcenyac dosage formulation in combination with Granger and Church for adsorption of residual opioid in the patch and inactivating the medicament contained within the used patch because the idea of doing so would have logically followed from their having

been individually taught in the prior art to be useful as a disposable device to prevent the misuse of a transdermal dosage forms.

Applicant also argues that Granger fails to teach or suggest a patch construction that incorporates a barrier that is removed upon removal of the patch from the skin of a user.

This argument is not persuasive since the transdermal dermal patch which is applied and affixed to the skin as an adhesive matrix or layer containing the opioid dispersed therein reads on barrier layer. Adhesive layer is juxtaposed to the reservoir or said opioid for attachment of the dosage form to the skin when the dosage form is applied to the skin, opioid diffuses osmotically through delivery means and adhesive layer. When the transdermal patch is peeled off from the skin, it would obvious that the adhesive layer is also removed upon removal of the patch from the skin of a user.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr